September 21, 1999

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Dockets Management Branch
(HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

[Docket No. 98P-0683] Food Labeling: Health Claims;
Soy Protein and Coronary Heart Disease
64 Federal Register 45932, August 23, 1999

Dear Sir or Madam:

The National Food Processors Association (NFPA) submits the following comments to the docket referenced above. NFPA previously filed comments to this docket on January 25, 1999. Among other subjects, NFPA provided comments related to the proposed method for assuring compliance with the health claim on soy protein and coronary heart disease.

NFPA is the principal scientific trade association representing the $460 billion food processing industry. With three laboratory centers, NFPA is the leading authority on food science and safety for the food industry. For more than 90 years, the food industry has relied on NFPA for government and regulatory affairs representation, scientific research, technical services, education, communications, and crisis management.

NFPA supports the establishment of the health claim regarding soy protein and coronary heart disease, and we support he broad availability of this health claim. NFPA has reservations, however, concerning the proposed compliance methodology, which we elaborate in detail below.

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Assuring Compliance with Soy Protein Content Eligibility Criterion -- Records Access

NFPA opposes the provision of the proposed regulation (proposed 21 CFR§101.82(c)(2)(ii)(B)) that would create FDA records inspection authority

for assuring compliance with the soy protein eligibility criterion for the health claim for products that contain a source of protein other than soy. NFPA believes that this proposed provision for compliance is crafted in an overly broad manner. NFPA proposed an alternate approach for compliance, along with alternate regulatory language. NFPA does not object to the compliance procedure outlined in the same subsection for products whose sole source of protein is soy.

NFPA, on behalf of its members, consistently and vigorously has maintained that FDA does not have broad records inspection authority, with a few explicit, statutorily authorized exceptions. Most recently, in 1996, NFPA commented in strong opposition to the proposed rule regarding authorized records access during establishment inspections to determine support for certain types of nutrient content claims and health claims. Those comments (Docket No. 95N-0103, 61 Federal Register 3885, February 2, 1996) were filed April 17, 1996. We reiterate the position expressed in those comments as regards this proposed rule.

FDA historically has acknowledged that it lacks statutory authority to inspect general food plant records, for example, in the preambles to the nutrition labeling rule and the proposed rule regarding records inspection to determine support for certain health claims and nutrient content claims (58 FR 2079 at 2110 (January 6, 1993); 61 FR 3885 at 3887 (February 2, 1996)); see also FDA Oversight -- Food Inspection: Hearings Before the Subcomm. on Public Health and Environment of the House Comm. on Interstate and Foreign Commerce, 92d Cong., 1st Sess. 130-131 (1971) (FDA Bureau of Foods Director, Virgil Wodicka, stating, "the Agency has a number of times asked for [records] authority .. . and the Congress has never felt that this was a necessary authority. As a consequence, we are able to look at . . . records only from those companies that will voluntarily show them"); Food Safety and Nutrition Amendments of 1978: Hearings on H.R. 10358, H.R. 42, H.R. 2180, H.R. 3290, H.R. 5173, and H.R. 5361 (and All Other Identical and Similar Bills) Before the Subcomm. on Health and the Environment of the House Comm. on Interstate and Foreign Commerce, 95th Cong., 2d Sess. 310

(1978) (FDA Chief Counsel Richard Cooper stating "food processors are not required to permit FDA to inspect food processing records that may bear on whether products are adulterated or misbranded").

Where Congress has deemed records inspection to be important to the effective implementation of the Federal Food, Drug, and Cosmetic Act (FFDCA), it has provided specific, statutory authority, as is the case, for example, with infant formula, prescription drugs, and restricted medical devices. See 94 Stat. 1190 (1980), 76 Stat. 780 (1962), 90 Stat. 539 (1976). These amendments would not have been necessary if broad records inspection authority was provided implicitly in either the general inspection provisions of FFDCA section 704(a) or under section 701(a).

The cases cited by FDA in the preamble to the current proposed rule provide no support for its proposal. In *Toilet Goods Association* v. *Gardner*, 387 U.S. 158, 163-64 (1967), the Supreme Court held that the case was not ripe for review and never reached the question of FDA's authority to inspect manufacturing facilities and processes. *National Confectioners Association* v. *Califano*, 569 F.2d 690 (D.C. Cir. 1978) concerned record keeping requirements and provides no support for FDA's proposal that it may inspect food records.

NFPA does not dispute FDA's assertion that information known to food processors would be needed to demonstrate compliance with the soy protein - coronary heart disease health claim eligibility criterion for products containing a protein source(s) in addition to soy. NFPA and its members recognize that it is the food processor's responsibility to be able to substantiate all claims made on food labels and in labeling and advertising. Recognizing the manufacturer's responsibility for the substantiation of claims, however, is quite different from acquiescing to FDA's creation of regulatory authority to inspect and copy any records the Agency deems necessary to substantiate those claims. NFPA urges FDA to consider, in finalizing this proposed rule, that the necessary substantiation may be provided through an alternate approach.

In those instances where labeling prospectively bears a soy protein - coronary heart disease health claim, food companies will recognize it is in their best interest to provide the substantiation for the claim to FDA upon request. The extensive enforcement powers of the Agency, including strict criminal liability, injunction, and seizure, provide a powerful incentive for manufacturers to assure the truthfulness of product labeling and to provide information substantiating all labeling claims. The food processing industry long has been responsible for the accuracy of all food label information. In the past, and at the present time, FDA's questions about label elements have been answered through industry cooperation.

In testimony before Congress, FDA has acknowledged that the food industry cooperates with FDA in this way. For example, FDA Commissioner Larrick stated that, despite the Agency's lack of records inspection authority, "the great bulk of American industry deals with [the Agency] forthrightly and does not hesitate to give up [the] information [FDA needs]" on a voluntary basis. Drug Industry Act of 1962: Hearings on H.R. 11581 and H.R. 11582 Before the House Comm. on Interstate and Foreign Commerce, 87th Cong., 2d Sess. 60, 73 (1962).

NFPA believes that virtually the entire food processing industry continues to cooperate with FDA in this manner, subject only to industry members' insistence that FDA present its requests for information by letter to the company's headquarters, rather than distract production facility personnel from their tasks by presenting such requests in the course of facility inspections. Since the vast majority of industry members maintain at headquarters facilities, and not at their plants, the type of information FDA would be seeking in this situation, NFPA believes that this approach reasonably balances the Agency's need to obtain information with the company's need to conduct its business in an orderly and predictable fashion.

Accordingly, NFPA believes that it would be reasonable for FDA to develop a final rule that directs food processors to substantiate any soy protein-coronary heart disease health claim that they may make on a label or in labeling, and to

provide substantiation to FDA within a reasonable period of time following the submission of a written request for the information to the company's headquarters facility. This alternative approach would service the purpose of providing FDA access to the necessary records, without purporting to create a broad records inspection authority that is not countenanced under the FFDCA and is not necessary for the efficient enforcement of the Act.

NFPA points out that FDA has adopted an alternate approach for compliance with food claims criteria in several places in regulations, most notably in the compliance provisions for the basis of nutrient reference values in comparative nutrient content claims, at 21 CFR §101.13(j)(ii)(A), and in compliance provisions for nutrient content claims and health claims made for restaurant foods, in 21 CFR §§101.13(q)(5)(ii) and 101.14(d)(2)(vii)(B). In these subsections, the firm that makes the claim is responsible for maintaining substantiation that the food qualifies for the claim, and the firm is required to make this substantiation available to appropriate regulatory officials upon request. The Agency established these compliance provisions under its general statutory authorities; no special authorization was required. It is this approach that NFPA envisions as an ideal approach for compliance with the conditions of the soy protein - coronary heart disease health claim in those instances when the protein content of the food includes sources in addition to soy.

To effectuate this approach, NFPA recommends that proposed §101.82(c)(2)(ii)(B) be amended to read as follows:

> FDA will assess qualifying levels of soy protein in the following fashion: FDA will measure total protein content by the appropriate method of analysis given in the "Official Methods of Analysis of the AOAC International," as described at 21 CFR 101.9(c)(7). Interested persons can obtain copies of the "Official Methods of Analysis of the AOAC International" from the Association of Official Analytical Chemists, 481 North Frederick Ave., Suite 500, Gaithersburg, MD 20877-2504, or may examine copies at the Center for Food Safety and Applied

Nutrition's Library, 200 C St. SW., Rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., Suite 700, Washington, DC. For products that contain no sources of protein other than soy, FDA will consider the amount of soy protein as equivalent to the total protein content. For products that contain a source or sources of protein in addition to soy, FDA will, using the measurement of total protein content, calculate the soy protein content based on the ratio of soy protein ingredients to total protein ingredients in the product. FDA will base its calculation on information supplied by manufacturers, such as nutrient data bases or analyses, recipes or formulations, purchase orders for ingredients, or any other information that reasonably substantiates that the soy protein content is in compliance with this regulation. Information sufficient to substantiate any such claim must be available for as long as the product bearing the claim is marketed. In addition, upon written request to a manufacturer's corporate headquarters location, the manufacturer must within thirty (30) days of receiving the request, supply such substantiating records or information to FDA.

~~FDA will base its calculation of the ratio of soy protein ingredients to total protein ingredients on manufacturers information such as nutrient data bases or analyses, recipes or formulations, purchase orders for ingredients, or other reasonable bases. Manufacturers must maintain records that permit such calculations for as long as the products are marketed. Manufacturers must make these records available for authorized inspection and copying by appropriate regulatory officials and manufacturers must submit these records to those regulatory officials upon request.~~

NFPA notes that, in addition to providing FDA, upon request, with information regarding substantiation of the claim, food processors may, on a voluntary basis, present information on the food label or in labeling that may support the claim and facilitate an FDA compliance review. This additional voluntary information could take the form of statements about the percentage composition of soy protein in a serving of food. Such an approach would also provide useful information to consumers, who, in the case of foods with protein sources in addition to soy, will not be able to rely on the nutrition label declaration of protein to provide complete information on soy protein content.

NFPA repeats its recommendation, expressed in the January 1999 comments on the proposed health claim, that FDA, in cooperation with the industry and AOAC, should investigate improvements to this soy protein analytical method so that ultimately it can be used as a reliable means to determine scientifically the amount of soy protein in the food that bear the claim. Not only would this approach enhance enforcement of the claim, but food companies would be able to use a reliable scientific technique as a quality control, to affirm the amount of soy protein in the food, and thereby ensure that the claim is truthful.

Technical Issue Regarding the Nutrition Labeling Declaration of Protein

The proposed rule has elicited several questions from NFPA members regarding the nutrient declaration of protein. It is clear that food processors making the soy protein - coronary heart disease health claim would be required to declare the corrected amount of protein, and percent Daily Value of protein, on their nutrition labels, in accordance with 21 CFR §101.9(c)(7)(i). Proposed §101.82(c)(1) requires compliance with the requirements of §101.14, the general rules governing health claims, and §101.14(d)(3) requires compliance with nutrition labeling rules of §101.9. The effect of the requirement to correct the amount of protein declared on the nutrition label will mean, in nearly all cases, the amount of protein declared will be lower than the quantity of protein present in the food product. In some instances, this may cause the declaration for protein in Nutrition Facts to be lower than

the amount of soy protein needed to qualify for the health claim. This is particularly the case when the sole source of protein in the food is soy protein.

In order to clarify this issue for the food industry, NFPA respectfully requests that FDA elaborate on this point in the preamble to the final rule. In particular, with respect to soy protein content compliance, NFPA urges FDA to clarify that compliance with the conditions of the soy protein - coronary heart disease health claim is to be based on the actual amount of soy protein present in the food, in accordance with the appropriate AOAC method for total protein content, or in accordance with compliance procedures for foods containing soy and additional protein sources, and not on the amount of protein declared on the nutrition label.

Thank you for this opportunity to comment on these important matters.

Sincerely,

Regina Hildwine
Director, Food Labeling and Standards
Regulatory Affairs